



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|------------------------------|------------------|
| 10/026,393 | 12/21/2001 | Stephen Quirk | 11301-1170 (44039-250928) | 1033 |
| 22827 | 7590 | 01/26/2005 | EXAMINER SWOPE, SHERIDAN | |
| DORITY & MANNING, P.A. POST OFFICE BOX 1449 GREENVILLE, SC 29602-1449 | | | ART UNIT 1652 | PAPER NUMBER |
| DATE MAILED: 01/26/2005 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/026,393

Applicant(s)

QUIRK ET AL.

Examiner

Sheridan L. Swope

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-61 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 46-61 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>1104</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 46-61 are pending.

Specification-Brief Description of the Figures

Objection to the Brief Description of the Figures is maintained. It is acknowledged that the text of the specification, in some cases, provides an explanation of the figures. However, the public should not have to search through the specification for said explanation. The Brief Description of the Figures should define all labeling in the figures. Correction is required.

Claim Rejections - 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 USC 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 48-50 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claim 48, it is unclear whether the signal element and antibody are both bound directly, and independently to the particle or whether the signal element is bound to the antibody and the signal element/antibody complex is bound to the particle. Claims 49-50, as dependent on Claim 48, are rejected for the same reasons. Clarification is required. For purposes of examination, it is assumed that the signal element is bound directly to the target antibody and the signal element/antibody complex is bound to the particle.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 USC 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1652

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Rejection of Claims 18-22, 24, and 25 under 35 USC 102(b) as being anticipated by Sorsa et al, 1998 (IDS) is withdrawn, as said claims have been cancelled. However, Claims 46-52 and 54-59 are herein rejected under 35 USC 102(b) as being anticipated by Sorsa et al, 1998. Sorsa et al teach a method for detecting the matrix metalloproteinase-8 (MMP-8), which uses an immunochromatographic lateral flow technique. A first antibody to MMP-8 is coated onto particles and acts as a label that can be detected, for example, by its fluorescent or chemiluminescent properties. Said particle can be any one of latex beads, colloidal metal, polystyrene, or *S. aureus* (col 13, lines 11-14). A sample of an oral swab from an individual having periodontal disease is applied to a reservoir of a capillary support/membrane system. The label/antibody/particles, which are applied to a membrane reservoir, migrate by diffusion coming in contact with and binding any MMP-8 in the sample. Further diffusion of the label/antibody/particle/MMP-8 complex brings the complex into contact with a second antibody that has been attached in a zone-like area of the membrane. When the liquid flow, carrying the complex migrates through this zone, label/antibody/particle complexes that have bound antigen are bound to the zone. Thus, the zone is detectable if MMP-8 is present in the sample (Abstract; col 22, lines 19-45). Therefore, Claims 46-52 and 54-59 rejected under 35 USC 102(b) as being anticipated by Sorsa et al, 1998.

Rejection of Claims 18-21, 24, and 25 under 35 USC 102(b) as being anticipated by Golub et al, 2000 (IDS) is withdrawn, as said claims have been cancelled. However, Claims 46-52 and 54-59 are herein rejected under 35 USC 102(b) as being anticipated by Golub et al, 2000. Golub et al teach (Abstract; col 22, lines 25-52) a method for detecting the matrix

Art Unit: 1652

metalloproteinase-13 (MMP-13), which uses the same technology described in Sorsa et al, 1998. Therefore, Claims 46-52 and 54-59 rejected under 35 USC 102(b) as being anticipated by Golub et al, 1998.

In support of their request that the original rejection of Claims 18-22, 24, and 25 under 35 USC 102(b) as being anticipated by Sorsa et al, 1998 and rejection of Claims 18-21, 24, and 25 under 35 USC 102(b) as being anticipated by Golub et al, 2000, Applicants provide the following arguments, which are relevant the rejection of Claims 46-52 and 54-59 under 35 USC 102(b) as being anticipated by Sorsa et al, 1998 or Golub et al, 2000, and rejection of Claims 53, 60, and 61 under 35 USC 103(a) as being unpatentable over Sorsa et al, 1998 in view of Rowe et al, 1999 and further in view of Vu et al, 2000 (see below), as stated herein.

Applicants argue that the methods for diagnosing “periodontal disease” as taught by Sorsa et al, 1998 or Golub et al, 2000 do not disclose the presently claim method for detecting the presence of a proteinase enzyme in a chronic wound (Applicant’s emphasis). For example, the present claims require the step of “collecting a sample from the fluid of a chronic wound” and then identifying the proteinase enzyme in such a fluid.

These arguments are not found to be persuasive for the following reasons. A person of ordinary skill in the art would know that periodontal disease is considered to be a condition comprising a chronic wound. Evidence that one of skill in the art would have said knowledge, is provided by Wikesjo et al, 1999 who review periodontal wound healing and regeneration. Furthermore, of particular relevance to the instant application, Graber et al, 1999 provide a review for the role of extracellular matrix proteinases in periodontal wound healing. Therefore, one of skill would know that periodontal disease comprises a chronic wound. In addition, in

Art Unit: 1652

each of Sorsa et al, (col 11, lines 45-47) and Golub et al, (col 10, lines 38-40) a fluid sample from the wound was collected and analyzed for the presence of a proteinase enzyme.

Rejection of Claims 18, 19, 21, 22, and 25 under 35 USC 102(b) as being anticipated by Maliszewska et al, 2001 is withdrawn because said claims have been canceled. Said rejection is also not found to be relevant to Claims 46-61 because said claims specifically recite a method comprising collecting a sample from the fluid of a chronic wound, while, in contrast, Maliszewska et al collect the sample from the CSF, not a wound.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 USC 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Rejection of Claim 23 under 35 USC 103(a) as being unpatentable over Sorsa et al, 1998 in view of Rowe et al, 1999 and further in view of Vu et al, 2000 is withdrawn, as said claims have been cancelled. However, Claims 53, 60, and 61 are herein rejected under 35 USC 103(a) as being unpatentable over Sorsa et al, 1998 in view of Rowe et al, 1999 and further in view of Vu et al, 2000. The teachings of Sorsa et al are described above. Sorsa et al does not teach a method for detecting a plurality of proteinases in a sample. Rowe et al teach a method for detecting a plurality of proteins in a mixed sample using an array of capture antibodies specific for three different proteins. After incubation with the mixed sample, the binding of each specific protein to its respective capture antibody is detected by a fluorescently-labeled target antibody, which binds to the same specific protein. In this manner, the presence of each of a plurality of

Art Unit: 1652

proteins in a mixed sample is detected (Fig 4). It would have been obvious to a person of ordinary skill in the art to incorporate the array technique of Rowe et al into the methods of Sorsa et al. In such a combined method, an array of capture antibodies to a plurality of proteases would be used to bind a plurality of proteases in a mixed sample, which would be detected using fluorescent or chemiluminescent target antibodies to the proteases. Motivation to do so is derived from the fact that proteases are involved in a plethora of normal and abnormal human conditions (Vu et al, 1999) and that the array would allow efficient determination of which proteases are present in patient samples. The expectation of success is high, as both the use of capture-antibody arrays to detect a plurality of proteins and the use of capture antibodies to detect proteases are known in the art. Therefore, Claims 53, 60, and 61 are rejected under 35 USC 103(a) as being unpatentable over Sorsa et al, 1998 in view of Rowe et al, 1999 and further in view of Vu et al, 2000.

Applicants did not specifically comment on the rejection of Claim 23 under 35 USC 103(a) as being unpatentable over Sorsa et al, 1998 in view of Rowe et al, 1999 and further in view of Vu et al, 2000,

Rejection of Claims 20, 24, and 25 under 35 USC 103(a) as being unpatentable over Maliszewska et al, 2001 in view of Sorsa et al, 1998 is withdrawn because said claims have been canceled. Said rejection is also not found to be relevant to Claims 46-61 because said claims specifically recite a method comprising collecting a sample from the fluid of a chronic wound, while, in contrast, Maliszewska et al collect the sample from the CSF, not a wound.

Art Unit: 1652


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943.

The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Sheridan Lee Swope, Ph.D.


REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1600-
1610